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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,084	12/03/2003	Wade E. Keller	RADNT-013C2	6046

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EXAMINER

GIBSON, ROY DEAN

ART UNIT PAPER NUMBER

3739

DATE MAILED: 03/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/727,084

Applicant(s)

KELLER ET AL.

Examiner

Roy D. Gibson

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 06 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-15, 19, 20 and 36-39 is/are rejected.
- 7) ☐ Claim(s) 16-18 and 21-35 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 12/03/2003.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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**DETAILED ACTION*****Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-63 of U.S. Patent No. 6,264,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are merely broader.

***Claim Rejections - 35 U.S.C. § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent

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granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-15, 19-20 and 36-39 are rejected under 35 U.S.C. 102(b) as anticipated by

Gobin et al. (6,126,684)

As to claims 1-10 and 19-20, Gobin et al. disclose a heat exchange catheter comprising:

a longitudinal catheter shaft (10) with proximal and distal ends;

a heat exchange region comprising a plurality of heat exchange elements (at least three as shown in Figures 4, 7-8 and 17-19, # 198 comprising hollow tubes forming a fluid flow path therethrough and evenly circumferentially distributed about the shaft) each having a length and opposed ends and each being disposed to permit body fluid to circumferentially surround at least a portion of each element when the catheter is positioned in a body lumen (col. 9, line 39-col.10, line 12 and col. 6, lines 29-60).

As to claim 3, Gobin et al. further disclose in the embodiment of Figures 7-9, heat exchange elements that are non-linear in cross-section.

As to claims 4 and 5, Gobin et al. further disclose the shaft has inflow and outflow lumens (52 and 54) and a circulation pathway therebetween for the circulation of a medium through the heat exchange elements via inflow orifices and opposing outflow orifices (Figures 7-9).

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As to claim 6, Gobin et al. further disclose in Figure 19 that the heat exchange elements extend in a non-linear path with points of inflection.

As to claims 7-10, Gobin et al. further disclose the structural elements of these claims in Figures 18 and 19.

As to claims 11-15, Gobin et al. further disclose various heat exchange elements with varying lengths relative to the length of the shaft of the catheter, and the examiner maintains that size is generally not a patentable feature especially as it relates to medical devices which can be designed for specific applications wherein the size fits the procedure and the dimensions of the patient.

The shaft section (40) is typically made from a polymeric material which is inherently an insulator to limit the heat loss to the surrounding tissue from the catheter hub (50) to the heat exchange elements.

As to claims 36-39, Gobin et al. further discloses a method of using the heat exchange catheter essentially as claimed.

### ***Allowable Subject Matter***


Claims 16-18 and 21-35 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

**Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy D. Gibson whose telephone number is 571-272-4767. The examiner can normally be reached on M-F, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on 571-272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Roy D. Gibson  
Primary Examiner  
Art Unit 3739

March 14, 2005